K082304

ST. JUDE MEDICAL
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AUG 27 2008

510(K) SUMMARY

1. ADMINISTRATIVE INFORMATION

Name:	St. Jude Medical
Address:	14901 DeVeau Place Minnetonka, MN 55345
Phone:	763-383-2640
Fax:	763-383-2556
Contact Person:	Jeff Sturm Principal Regulatory Affairs Specialist
Date:	August 6, 2008

2. DEVICE INFORMATION

Name of Device:	Roll-X™ Guidewire
Common Name:	Coronary Guidewire
Classification Name:	Catheter Guide Wire (870.1330)
Product Code:	DQX

3. PREDICATE DEVICE INFORMATION

Asahi Prowater PTCA Coronary Guidewire (Abbott)- K052339 cleared Nov 2005

Hi-Torque Balanced Middleweight Universal (Abbott)- K013833 cleared Jan 2002

4. DEVICE DESCRIPTION

Roll-X™ Guidewire is a steerable guide wire constructed of a stainless steel core wire and a coiled wire design at the distal end. The core wire is PTFE coated. The Roll-X Guidewire has a unique distal end design to enhance torque response and control. The distal end of the guidewire is shapeable and is radiopaque. The guide wire is provided sterile and non-pyrogenic.

5. INTENDED USE

The Roll-X Guidewire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of compatible stent devices during therapeutic intravascular procedures. The guidewire is not to be used in the cerebral blood vessels.

6. TECHNOLOGICAL CHARACTERISTICS

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the currently marketed predicate devices.

7. SUMMARY OF NON-CLINICAL TESTING

Non-clinical testing of the Roll-X™ Guidewire includes in vitro bench testing, animal evaluation, biocompatibility testing, shelf-life and package testing and sterilization evaluation. Results of the testing demonstrate that the guidewire design meets product specifications and intended uses.

8. SUBSTANTIAL EQUIVALENCE CONCLUSION

The Roll-X™ Guidewire described in this 510(k) is substantially equivalent to the ASAHI Prowater PTCA Coronary Guidewire (K052339) and Hi-Torque Balanced Middleweight Universal Guidewire (K013833). The intended use, design, material types, technology, and performance of the Roll-X™ Guidewire is equivalent to the predicate devices. There are no differences between devices which would raise issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2008

St. Jude Medical
c/o Mr. Jeff Sturm
Principal Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, MN 55345

Re: K082304
Trade/Device Name: Roll-X™ Coronary Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: August 12, 2008
Received: August 13, 2008

Dear Mr. Sturm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volkmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082304

Device Name: Roll-X™ Coronary Guidewire

Indications for Use:

Roll-X Coronary Guidewires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of compatible stent devices during therapeutic intravascular procedures. The Guidewire is not to be used in the cerebral blood vessels.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Shuel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082304